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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,521	04/20/2004	Daniel Bar-Shalom	028232-0107	2760

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EXAMINER	
MAHYERA, TRISTAN J	
ART UNIT	PAPER NUMBER
4173	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,521	BAR-SHALOM, DANIEL	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-27 are pending. Claims 1-27 are examined on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(a-d) as follows:

In order to receive the benefit of the earlier foreign filing date applicant must supply a certified copy of DK 0222/94 filed on 2/23/1994. Therefore, the earliest U.S. effective filing date as determined by the Examiner is 2/23/1995.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the inventive characteristics to which the claims are directed.

The use of the trademarks CUMAR, CLORAFIN, PICCOLASTIC, PICCOLASTIC, FLEXOL, PARACRIL and CARBOWAX have been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. See page 8 line 34; page 9 line 1, line 4 and line 24.

Appropriate correction is required.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 2-27 are objected to because of the following informalities: Dependent claims must not use the article "A" when beginning the preamble. Appropriate correction is required. Examiner suggests replacing "A" with "The".

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "cellulose derivative" is vague and indefinite. The term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound. Although there are examples in the specification of

cellulose derivatives (page 6, lines 33-35; page 7 lines 10-26), these are not limiting and the specification fails to provide a limiting definition of the above phrase.

Claims 2-27 are rejected as depending from rejected Claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8 and 12-27 are rejected under 35 U.S.C. 102(b) as being anticipated by BAR-SHALOM et al. (US 5,213,808 - see PTO-892).

BAR-SHALOM teaches a controlled release pharmaceutical composition that provides a controlled and constant release of an active substance embedded in a matrix layer that erodes in an aqueous medium and at least one coating layer that crumbles or erodes upon exposure to an aqueous medium. See e.g. column 3 lines 21-66; instant claims 1 and 23. Simple extrusion or injection molding is used to make the compositions. See e.g. column 5 lines 15-19; instant claim 4. The matrix comprises an active substance. See e.g. column 2 lines 40-43; instant claims 1 and 23. The coating has at least one opening exposing the matrix. See e.g. column 3 lines 64-66; instant claims 1 and 23. The coating comprises a cellulose derivative, specifically cellulose acetate. See e.g. column 16 lines 26-38, specifically line 28; instant claims 1, 8, 23 and

24. The coating is further composed of a water soluble antioxidant, citric acid. See column 16 line 63; instant claim 17. Fillers are provided. See column 10 lines 14-59; instant claims 1, 15, 16, 23 and 27. Plasticizers are provided. See e.g. column 14 lines 31-32; instant claims 1, 12, 13, 14, 23 and 26. The matrix when exposed erodes at a constant rate. See e.g. column 12 lines 15-20; instant claim 2. The coating erodes at a slower rate than the matrix. See e.g. column 12 lines 57-66; instant claim 3. BAR-SHALOM further teaches the cellulose to be methylcellulose or carboxymethylcellulose. See e.g. column 16 lines 51-52; instant claims 9 and 25. Plasticizers include sorbitol, glycerin, non-ionic surfactants, fatty acids or fatty alcohols, polyethylene glycol, ethers of cetyl and cetostearyl alcohol and polyethylene glycol stearate. See e.g. column 14 lines 32-35; claims 14-19; instant claims 13, 14, 18, 22 and 26. The polyethylene glycol has a molecular weight of at least 20,000 daltons, or less than 20,000 daltons. See e.g. column 10 line 66 to column 11 line 12; instant claims 19-21. The polyethylene glycol is crystalline. See e.g. column 10 lines 62-66; column 3 lines 35-45 and claim 14; instant claims 18.

Therefore, each and every element of the claims is met by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-7, 9-11, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over BAR-SHALOM in view of SHIRAI et al. (US 5,082,669 – see PTO-892).

BAR-SHALOM teaches a controlled release pharmaceutical composition that provides a controlled and constant release of an active substance embedded in a matrix layer that erodes in an aqueous medium and at least one coating layer that crumbles or erodes upon exposure to an aqueous medium, as described above.

BAR-SHALOM does not explicitly teach cellulose ethers comprising at least one ethylcellulose wherein the ethoxyl content is in the range of 44.5-52.5%. BAR-SHALOM does not teach the use of the salt of carboxymethylcellulose or hydroxypropylmethylcellulose.

SHIRAI teaches a rapid-releasing oral pharmaceutical composition with a taste masking coating. See e.g. column 1 lines 7-9. The coating contains a pharmaceutical form of ethylcellulose. See e.g. column 4 lines 37-38; instant claim 5. This ethylcellulose has an ethoxyl content in the range of 46.5 to 51%. See e.g. column 4 lines 37-44; instant claims 6 and 7. The salt of carboxymethylcellulose is taught as a water swelling agent. See e.g. column 3 lines 43-44; instant claim 10. Hydroxypropylmethylcellulose is also taught as a water swelling agent. See e.g. claim1; instant claim 11.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice a pharmaceutical composition having a matrix containing an active and a controlled release coatings because BAR-SHALOM teaches it is within the skill of the art to use cellulose derivatives as a coating to improve the controlled release characteristics of the active and because SHIRAI teaches it is within the skill of the art to use ethylcellulose wherein the ethoxyl content is in the range of 44.5-52.5% and the salt of carboxymethylcellulose. One would have been motivated to do so in order to receive the expected benefit, as suggested by BAR-SHALOM. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22 and 29 of copending Application No. 10/845522. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant Claim 1 is directed to a composition for controlled delivery of at least one active substance into an aqueous medium by erosion at a preprogrammed rate of at least one surface of the composition comprising a matrix with the active substance and at least one coating having an opening that exposes at least one surface of the matrix. The coating comprises at least

a first cellulose derivative, and at least one of a second cellulose derivative, a plasticizer and a filler.

Copending claim 22 is directed to a composition for controlled delivery of at least one active substance into an aqueous medium by erosion at a preprogrammed rate of at least one surface of the composition comprising a matrix comprising the active substance, at least one soluble crystalline polymer and at least one enteric coating. Copending claim 29 which depends from claim 22 comprises a first cellulose derivative, and at least one of a second cellulose derivative, a plasticizer and a filler.

Although not identical, copending claim 22 and claim 29 contain all the limitations of instant Claim 1. As copending claim is a dependent claim it would have suggested or motivated a person having ordinary skill in the art to combine claims 22 and 29 into one claim thus creating all the limitations of Claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tristan J. Mahyera whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-4pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TJM/